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Goro Fujita

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EXAMINER

CROW, ROBERT THOMAS

ART UNIT

PAPER NUMBER

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,139	<b>Applicant(s)</b> FUJITA, GORO	
	<b>Examiner</b> Robert T. Crow	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11 September 2008 has been entered.

### ***Status of the Claims***

2. This action is in response to papers filed 11 September 2008 in which claim 1 was amended, no claims were canceled, and no new claims were added. All of the amendments have been thoroughly reviewed and entered.

The previous new matter rejections under 35 U.S.C. 112, first paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b)/35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1-6 are under prosecution.

3. The following rejections are new rejections necessitated by the amendments.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite in the recitation “wherein the detection units are arrayed in concentric circles or in a spiral shape when viewed from the top.” Claim 1, upon which claim 5 depends, requires the plurality of detection units to equally divide the substrate in a circumferential direction. However, two detection units arrayed in concentric circles or in a spiral shape, as required by claim 5, cannot equally divide the substrate in a circumferential direction because they are, as required by claim 5, are not aligned along the same circumference. Rather, two detection units arrayed in concentric circles or in a spiral shape, as required by claim 5, would be arrayed in circumferences in the substrate that have different lengths (i.e., the inner concentric circle or spiral is smaller than the outer concentric circle or spiral, thus having different lengths). It is suggested the claim be amended so that the shapes clearly equally divide the bioassay substrate in a circumferential direction.

***Claim Rejections - 35 USC §102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999).

Regarding claim 1, Wang et al teach a bioassay substrate. In a single exemplary embodiment, Wang et al teach the disc-shaped bioassay substrate of Figure 6, which is equally divided into 4 sectors 82 (column 14, line 60-column 15, line 10). The substrate further comprises optically interpretable recorded information in the form of header 86 (column 14, line 60-column 15, line 10). The disc further comprises a plurality of detection units comprising a data detecting area comprising a reaction area for performing a mutual reaction process between substances to be detected and a target substance; namely, Figure 6 shows the track 84 in each area 82, wherein the track comprises particles having a bound component thereon (column 6, lines 15-45), wherein the bound component is a nucleic acid (Figure 1A and column 3, lines 10-35). The area of the track comprising the area between the nucleic acid bearing particles is the claimed reaction area (Figures 5 and 6). The data detecting area further comprises a detection surface for fixing end portions of the substances to be detected in the form the area of the track to which the particles bearing the nucleic acids are attached

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(Figures 2C and 2D). The data detection area has a first length in a radial direction; namely, Figures 5 and 6 show the particles confined to track. The distance between each pair of track marks is the length in the radial direction.

It is noted that the claim requires “a detection surface for fixing end portions of the substances to be detected.” The claim therefore only requires an area for fixing, and does not actually require substances to be fixed to the area. Thus, the limitation “a detection surface for fixing end portions of the substances to be detected” merely recites an **intended use** of the detection surface.

Wang et al further teach a servo are formed in the detection unit without overlapping the data detecting area; namely, the servo area comprises the areas within the track comprising the header marks 86, which are separate from and non-overlapping with data detecting area (Figures 5-6). The header marks optically provide information on the data detecting area; namely, the sector and track number (column 14, line 60-column 15, line 10). The servo area has a first length in a radial direction; namely, Figure 6 shows header marks 86 each aligned within a track. The radial distance with track marks is the length in the radial direction, which is approximately equal to the radial length for the data detect because both the header and the particles are within the same track (Figure 6).

Regarding claim 2, Wang et al teach the substrate of claim 1, wherein the reaction area comprises a detection surface on which a surface treatment is performed to as to fix the substances to be detected; namely, solid support is prepared for attachment of the components (i.e., particles; column 2, lines 1-15).

Regarding claim 3, Wang et al teach the substrate of claim 1 wherein the substances to be detected and the target substances are nucleotides (Figure 1A and column 3, lines 10-35) and the mutual reaction process is hybridization (column 4, lines 10-35).

Regarding claim 4, Wang et al teach the substrate of claim 1 wherein the detection units are arrayed along the circumferential direction (Figures 5-6).

Regarding claim 5, Wang et al teach the substrate of claim 1 wherein the detection units are arrayed in concentric circles or spiral shapes; namely, the concentric tracks of Figure 6.

Regarding claim 6, the substrate of claim 1 is discussed above. Wang et al also teach the positional information comprises a tracking mark and an address mark; namely, the header marks optically provide the sector (i.e., address) and track number (column 14, line 60-column 15, line 10).

### ***Claim Rejections - 35 USC §103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iwasaki et al (Japanese Patent Application Publication No 2001-238674, published 9 April 2001) in view of Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999) as evidenced by the online dictionary at Merriam-Webster.com. Citations of Iwasaki et al are to the machine translation of the document provided by the National Center of Industrial Property Information and Training website [http://www.ipdl.ncipi.go.jp/homepg\\_e.ipdl](http://www.ipdl.ncipi.go.jp/homepg_e.ipdl). The machine translation of the document was provided with the previous Office Action mailed 4 January 2008.

Regarding claim 1, Iwasaki et al teach a bioassay substrate. In a single exemplary embodiment, Iwasaki et al teach the disc-shaped bioassay substrate of Figures 1 and 2, which comprises optically interpretable recorded information in the form of tracking marks 5 and address marks 6 (Description of the Drawings). The disc further comprises a plurality of detection units comprising a data detecting area comprising a reaction area for performing a mutual reaction process between substances to be detected and a target substance; namely, Figure 2 shows the partitioned area of a glass surface 8 following track mark 5 comprising spot 9 (Figure 2, paragraph 0049 of the Detailed Description, and the Description of the Drawings). The area of the glass surface is the reaction area, which further comprises a detection surface for fixing end portions of the substances to be detected in the form of spot 9, to which DNA molecules are fixed (paragraph 042 and 0049 of the Detailed Description, Figure 2, and the Description of the Drawings). The data detection area has a first length in a radial direction; namely, Figure 1b shows three rows of spots 9 each aligned



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between two track marks 5. The distance between each pair of track marks is the length in the radial direction.

It is noted that the claim requires “a detection surface for fixing end portions of the substances to be detected.” The claim therefore only requires an area for fixing, and does not actually require substances to be fixed to the area. Thus, the limitation “a detection surface for fixing end portions of the substances to be detected” merely recites an **intended use** of the detection surface.

Iwasaki et al further teach a servo are formed in the detection unit without overlapping the data detecting area; namely, the servo area comprises the areas between the track marks 5 which comprise the address marks 6, which are separate from and non-overlapping with spot 9 (Figure 1B and the Description of the Drawings). The address marks optically provide information on the data detecting area (paragraph 0064 of the Detailed Description). The servo area has a first length in a radial direction; namely, Figure 1b shows three rows of address marks 6 each aligned between two track marks 5. The distance between each pair of track marks is the length in the radial direction, which is approximately equal to the length used to confine the spots because both the spots 9 and the address marks 6 are within the pairs of tracking marks, which define the length in the radial direction.

In addition, the online dictionary at Merriam-Webster.com defines “pitch” as “the distance between any of various things.” Figure 1B of Iwasaki et al shows two tracking marks 5, and states that the pitch of the tracking mark is 25 micrometers (paragraph 0048 of the Detailed Description). Thus, the radial length of the track between the two

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tacking marks is interpreted as 25 micrometers, and the address marks (i.e., the servo area) is interpreted as having a radial length of 25 micrometers. Iwasaki et al also teach the spots are 25 micrometers (i.e., about 20-200 micrometers; paragraph 0004 of the Detailed Description). Thus, both the spot and the address mark have the same length in a radial direction (i.e., 25 micrometers) within a track having a radial length 25 micrometers.

Iwasaki et al do not explicitly teach the plurality of detection units equally divide the bioassay substrate in a circumferential direction.

However, Wang et al teach a bioassay substrate wherein a plurality of detection units equally divide the bioassay substrate in a circumferential direction; namely, Figures 5-6 of Wang et al show a bioassay disc equally divided into 4 sectors. Wang et al also teach the division of the disc into the separate areas has the added advantage of allowing greater flexibility in assaying sample while still providing rapidity and accuracy (column 14, lines 50-60). Thus, Wang et al teach the known technique of having a plurality of detection units that equally divide the bioassay substrate in a circumferential direction.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the disc having the plurality of detection units circumferentially arrayed as taught by Iwasaki et al so that the plurality of detection units equally divide the bioassay substrate in a circumferential direction as taught by Wang et al to arrive at the instantly claimed substrate with a reasonable expectation of success. The ordinary artisan would have been motivated to make the

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modification because said modification would have resulted in a disc having the added advantage of allowing greater flexibility in assaying sample while still providing rapidity and accuracy as explicitly taught by Wang et al (column 14, lines 50-60). In addition, it would have been obvious to the ordinary artisan that the known technique of using the plurality of detection units that equally divide the bioassay substrate in a circumferential direction as taught by Wang et al could have been applied to the disc of Iwasaki et al with predictable results because the plurality of detection units that equally divide the bioassay substrate in a circumferential direction as taught by Wang et al predictably results in an arrangement of detection units on the assay disc that allows for rapid analysis.

Regarding claim 2, the substrate of claim 1 is discussed above. Iwasaki et al teach the reaction area comprises a detection surface on which a surface treatment is performed to as to fix the substances to be detected; namely, the glass surface of the disc is treated with a silane so that DNA probes, which are the substances to be detected, are fixed (paragraph 0080 of the Means).

Regarding claim 3, the substrate of claim 1 is discussed above. Iwasaki et al also teach the substances to be detected and the target substances are nucleotides and the mutual reaction process is hybridization; namely, the disc detects hybridization between fixed DNA probes and target DNA (paragraphs 0015-0020 of the Detailed Description); DNA molecules are nucleotide chains.

Regarding claim 4, the substrate of claim 1 is discussed above. Iwasaki et al further teach the detection units are arrayed along the circumferential direction; namely,

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the partition comprising a mark and spot is arrayed in a concentric circle, and the partition divisions are carried out along the die-length (i.e., circumference; paragraphs 0049-0050 of the Detailed Description and Figures 1-2).

Regarding claim 5, the substrate of claim 1 is discussed above. Iwasaki et al teach the detection units (i.e., partitions) are arrayed in concentric circles or spiral shapes (paragraph 0050).

Regarding claim 6, the substrate of claim 1 is discussed above. Iwasaki et al also teach the positional information comprises tracking mark 5 and address mark 6, which are separate from a non-overlapping with spot 9 (paragraphs Figure 2 and the Description of the Drawings).

### ***Response to Arguments***

10. Applicant's arguments with respect to the previous rejections of the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

### ***Conclusion***

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571)272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert T. Crow/  
Examiner, Art Unit 1634

Robert T. Crow  
Examiner  
Art Unit 1634